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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/779,457	01/07/97	CARTER	P P0936F2

EXAMINER	
DRAPER, G	
ART UNIT	PAPER NUMBER
1812	37

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or ~~thirty~~ days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-39 is/are pending in the application.

Of the above, claim(s) 34-39 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-21, 25-33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-39 were are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

★ U.S. GPO: 1996-409-

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, drawn to antibodies to WSX receptors and compositions thereto, classified in class 530, subclass 387.1+.

II. Claims 34 and 35, drawn to method of in activating the receptor and enhancing cellular proliferation/differentiation classes 424 or 435, subclass vary depending on the specifies of the method and whether it is in vivo or in vitro.

III. Claims 36-39 are, drawn to Nucleic Acid (N.A.), vector, host and method of recombinant production of the antibody, classified in classes 536 and 435, subclasses 235 and 70.21 respectively.

Note: Consistent with the request of Wendy Lee during the telephone election, both of the methods of claims 34 and 35 have be grouped together as one inventive group.

The inventions are distinct, each from the other because:

Inventions Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies ,as claimed, can be prepared by conventional method using hybridoma. Further the N.A. can be used other than to make the antibodies such as their use as probes or in therapy.

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies as claimed can be used other than in the methods recited such as their use in other therapeutic and diagnostic methods such as immunoaffinity; or they can be used as probes.

It is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction is deemed to be proper because the products appear to constitute patentably distinct inventions. The inventive products of Groups I and III are directed to products that are structurally, physically and functionally distinct and determined to be patentable they would also be patentably distinct. Furthermore, these products are not required one for the other; nor are they each required for each of the methods of Groups II and III.

In a similar manner it is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive methods of Groups II and III require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods. Furthermore, these methods are not required one for the other; nor are they each required for each of the products of Group I and III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications which are not co-extensive. And there are different issues for the search and examination of each group, which would be unduly burdensome, accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Wendy Lee on 9-12-97 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-33. Affirmation of this election must be made by applicant in responding to this Office action. Claims 34-39 are

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. The disclosure is objected to because of the following informalities: The specification at page 79 and claims 10,13,16 and 19 are incomplete for failing to recite the deposit information. Further, since it appears that these deposits are necessary for the invention, applicants must ensure that there is full compliance with the Deposit Rules as set forth in chapter 2400 of the MPEP. A copy of the contract is also requested..

Appropriate correction is required.

3. Claim 3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite for failing to clearly define or characterize the WSX receptor variant 13.2. Merely referring to the particularly receptor (also known in the art to encompass or be directed to one of the ob/leptin receptor) by a number is insufficient to characterize the receptor. Further, there is no point of reference nor characterization, other than a name , abbreviation and/or acronym, thus, in the absence of such, the skilled artisan would not be able to make and antibody to the desired receptor with assurance that it will possess the desired binding affinity. Further, as is now known in the art, there are several and distinct variant forms of the leptin/ob receptor, but this number (13.2) fails to sufficiently identify which ob/leptin receptor the antibody of the claim binds, nor what the size, length or specific features are encompassed by this receptor. Further, since the art has also shown that the ob/leptin receptor varies in species, in this number also does not identify the specie form of the receptor.

4. Claims 1-9,11,14,17,20,25-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies to certain forms of the ob/leptin receptor, does not reasonably provide enablement for antibodies to any WSX receptor; 2) antibodies to any epitope and on any WSX receptor. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly directed to antibodies to the WSX receptor, but the specification is not enabled for such. According to applicant's disclose it would appear that the WSX receptor contemplated by the inventions is that which is now known as the leptin receptor(s). But the art has shown that hematopoietic cytokines bind to receptors that possess a WSX motif. While applicants have provided enablement for antibodies to certain variant and specie forms of the leptin/ob receptor, the production of these antibodies are not sufficient to reasonably predict the enablement (both production and use of any an all WSX receptor antibodies). Each of the various hematopoietins, that bind to receptor that have a WSX motif are structurally, functionally and characteristically distinct-which features are not predictable one from the other.

In addition, as stated above, there are various specie and variant forms of the ob/leptin receptor and because of the unique binding affinities for antibodies, one variant and/or specie form would not appear to be predictable from another.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-9 and 25-33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any one of Kishimoto et al, Park et al, or Burstein.

Each of the prior art disclose antibodies to certain cytokines that are known in the art as hematopoietic growth factors. Ksihimoto et al and Burstein disclose antibodies to the IL-6 receptor (see claims); while Park et al disclose antibodies to the IL-7 receptor (see the claims). The prior art does not expressly teach that these receptors are WXS receptor, however, it is well known in the art that many cytokines such as IL-6 and IL-7 are hematopoietins and that they bind to receptors that possess a WSX motif (see the art cited by applicants for such cytokine superfamily that possess the WSX motif as well as additional art cited as of interest herein). Thus, the prior art appears to meet the claim limitation for antibodies to WSX receptors, and the burden is upon applicants to establish a patentable difference (In re Best 195 USPQ 430). In the event the prior art antibodies do not have agonist activity or are neutralizing antibodies, or possess the claimed affinity, at the time of the invention it would have been prima facie obvious to make antibodies that possess these desired properties based on the advancement in the technology of antibody art.

6. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snodgrass et al.

Snodgrass et al disclose a novel hematopoietin receptor having a WSX motif, which is now known as one form of the Ob/leptin receptor (see the claims). At col 2. Lines 57-59 it is taught that this receptor can be used to screen for ligands or to make antibodies (col 5) . While Snodgrass et al did not expressly disclose antibodies to this WSX receptor, or the identity of the ligand as leptin, in view of the fact that the receptor has been identified as a hematopoietin receptor with a WSX motif, it would have been prima facie obvious to used this WSX receptor to make the various claimed antibodies that would possess all of the properties/characteristics of the

claims, consistent with the teachings in this prior art that antibodies to the WSX receptor could be made.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The other prior art listed on the 892 is cited as of interest to show related art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Draper, G. whose telephone number is (703) 308-4232.

Draper/sg

October 24, 1997

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800